

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

MASSACHUSETTS INSTITUTE)	
OF TECHNOLOGY and CHILDREN'S)	
MEDICAL CENTER CORPORATION,)	
Plaintiffs,)	
)	
v.)	1:13-CV-10020-MLW
)	
SHIRE PLC,)	
SHIRE PHARMACEUTICALS, INC., and)	
SHIRE REGENERATIVE MEDICINE, INC.,)	
Defendants.)	

MEMORANDUM AND ORDER

WOLF, D.J.

February 2, 2014

I. SUMMARY

On January 4, 2013, plaintiffs Massachusetts Institute of Technology ("MIT") and Children's Medical Center Corporation ("CMCC") filed this suit alleging patent infringement against defendants Shire Regenerative Medicine, Inc. ("SRM"), Shire plc ("Shire"), and Shire Pharmaceuticals, Inc. ("Shire Pharmaceuticals"). An amended complaint was filed on June 28, 2013.

MIT and CMCC are the joint assignees of the two patents at issue in this case: U.S. Patent No. 5,759,830 ("the '830 Patent"), which issued on June 2, 1998, and U.S. Patent No. 5,770,193 ("the '193 Patent"), which issued on June 23, 1998. The '830 Patent discloses and claims a "[t]hree-dimensional fibrous scaffold containing attached cells for producing vascularized tissue in vivo," while the '193 Patent discloses and claims a method for preparing such a fibrous scaffold.

The plaintiffs allege that the product Dermagraft – a skin substitute, derived from natal foreskin tissue, used to treat foot ulcers of diabetic patients – infringes the '830 and '193 Patents.¹ Dermagraft is produced and sold by defendant SRM, above which the other two defendants sit in the Shire corporate hierarchy. SRM is alleged to have directly infringed both patents, Am. Compl. ¶¶24, 29, and to have induced infringement of the '193 Patent, id. ¶30. Shire and Shire Pharmaceuticals are alleged to have induced infringement of both patents. Id. ¶25, 34. The alleged infringement by all three defendants is also alleged to be willful. Id. ¶¶26, 35.

SRM filed an answer and counterclaims. Shire and Shire Pharmaceuticals filed a motion to dismiss under Federal Rule of Civil Procedure P. 12(b)(2) for lack of personal jurisdiction and under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. With respect to the jurisdictional dispute, these defendants argue that they do not have sufficient contacts in Massachusetts for a finding of personal jurisdiction. See Memo. in Support of Mot. to Dismiss at 7. With respect to the alleged failure to state a claim, these defendants argue that the amended complaint lacks allegations sufficient to sustain the claims of induced and willful infringement. Id. at 14.

¹ An allegation of infringement of a third patent was included in the original complaint, but that content was omitted from the amended complaint.

For the reasons explained below, although the plaintiffs have made a prima facie showing that personal jurisdiction exists over these defendants, the motion to dismiss is being allowed because the pleadings fail to state claims of induced and willful infringement against Shire and Shire Pharmaceuticals. Accordingly, the court is allowing the motion to dismiss the claims against Shire and Shire Pharmaceuticals. However, the dismissal is without prejudice and plaintiffs are being provided an opportunity to file a second amended complaint, if there is a proper basis to do so. Shire and Shire Pharmaceuticals may move to dismiss that complaint if they believe it is deficient.

Because this motion was discussed at the scheduling conference on January 24, 2014, no further argument is necessary, and the defendants' motion for oral argument on the motion to dismiss (Docket No. 28) is being denied as moot.

II. PERSONAL JURISDICTION

A. Legal Standard

In patent cases, the court applies Federal Circuit law to motions to dismiss for lack of personal jurisdiction. See 3D Sys., Inc. v. Aarotech Labs., Inc., 160 F.3d 1373, 1377 (Fed. Cir. 1998).

Where, as here, the parties have not conducted jurisdictional discovery, a plaintiff needs to make only a "'prima facie showing' of jurisdiction to defeat a motion to dismiss." Trintec Indus., Inc. v. Pedre Promotional Prods., Inc., 395 F.3d 1275, 1282 (Fed.

Cir. 2005) (quoting Silent Drive, Inc. v. Strong Indus., Inc., 326 F.3d 1194, 1201 (Fed. Cir. 2003)). "In the procedural posture of a motion to dismiss, a district court must accept the uncontroverted allegations in the plaintiff's complaint as true and resolve any factual conflicts in the affidavits in the plaintiff's favor." Elecs. for Imaging, Inc. v. Coyle, 340 F.3d 1344, 1349 (Fed. Cir. 2003) (emphasis added); see also Grober v. Mako Prods., Inc., 686 F.3d 1335, 1345 (Fed. Cir. 2012).² However, the plaintiff "is entitled to only those inferences that are reasonable." Autogenomics, Inc. v. Oxford Gene Tech. Ltd., 566 F.3d 1012, 1018 (Fed. Cir. 2008).

B. Facts

The uncontroverted allegations found in the amended complaint, as well as the evidence presented in the parties' affidavits, construed in the light most favorable to the plaintiffs, are as follows.

Although SRM has not challenged this court's exercise of personal jurisdiction, its corporate structure and activities are relevant to the jurisdictional inquiry for the other two defendants. SRM is a Delaware corporation with its principal place

² This standard differs materially from the one ordinarily employed by this court. The First Circuit has long held that even when "the defendant does not present evidence to contradict the allegations . . . [,] plaintiffs may not rely on unsupported allegations in their pleadings to make a prima facie showing of personal jurisdiction." Boit v. Gar-Tec Prods.Inc., 967 F.2d 671, 675 (1st Cir. 1992).

of business in California. Am. Compl. ¶3. SRM is the actual producer, seller, and marketer of Dermagraft, id. ¶8, and the complaint alleges that "SRM has marketed, placed, and continues to market and place medical products, including the accused product in this case, into the stream of commerce . . . with the knowledge, intent, and/or understanding that such products are marketed and/or sold within this District," id.

Shire is incorporated in the Bailiwick of Jersey, with its principal place of business in Ireland. Id. ¶5. It is an indirect corporate parent of both SRM and Shire Pharmaceuticals, and the complaint alleges that it "is involved in the manufacturing, marketing, and selling of the accused product in this case." Id. ¶9.³ The plaintiffs have filed a June 12, 2013 Boston Globe article, entitled "CEO Calls Being in Mass. Crucial for Shire to Innovate," that explains that Shire's CEO and "chief innovation driver," Dr. Flemming Ornskov, conducts extensive business in Massachusetts and takes a "hands-on approach" to managing the company and its subsidiaries, including the company's "regenerative

³ In support of the motion to dismiss, the defendants have provided as evidence an affidavit by Shire's Group Corporate Counsel, who states that "Shire plc is not involved in the day-to-day operations of manufacturing, selling, or distributing Dermagraft." Stewart Decl. ¶7 (emphasis added). However, because this statement does not expressly challenge the assertion that Shire is "involved" in those operations, the plaintiffs' allegation is "uncontroverted," permitting the court to consider it under the prima facie standard. See Elecs. for Imaging, 340 F.3d at 1349.

medicine" division, evidently SRM. Cataldo Decl. Ex. A. The plaintiffs have also submitted a May 2013 Shire press release that identifies Dr. Ornskøv as the chair of Shire's "In-Line" group of business units, including the regenerative medicine unit. Cataldo Decl. Ex. B. at 4. The press release also indicates that under Dr. Ornskøv's leadership, the business units in the "In-Line" group would be "supported by a single technical operations group and simplified, centralized corporate functions." Id.

Shire Pharmaceuticals is the direct corporate parent of SRM. Am. Compl. ¶10. It is a Delaware entity with its principal place of business in Pennsylvania. Id. ¶4. The amended complaint alleges that Shire Pharmaceuticals "engages in continuous and systematic contacts with the Commonwealth of Massachusetts," is "involved in the manufacturing, marketing and selling of the accused product in this case,"⁴ and "has caused and continues to cause injury to Plaintiffs in Massachusetts based on its infringement within and outside of Massachusetts." Id. ¶10. The plaintiffs argue that Shire Pharmaceuticals controls the hiring and sales force at SRM, arguing that the company "exercises direct

⁴ Mirroring the evidence offered by Shire, Shire Pharmaceuticals has offered the affidavit of one of its officers and managers, who declares that "Shire Pharmaceuticals is not involved in the day-to-day operations of manufacturing, selling or distributing Dermagraft." Rosenberg Decl. ¶5 (emphasis added). Again, this statement does not directly controvert the plaintiff's allegation that Shire Pharmaceuticals is generally involved with the Dermagraft business, which is conducted from Massachusetts.

control" over SRM. Opp. to Mot. at 8. In support of this claim, the plaintiffs offer evidence that the company manages the hiring and staffing operations for SRM, including for positions in Massachusetts. See Cataldo Decl. Exs. D, E, & F. One such job listing, seeking a Reimbursement Territory Manager for Boston, explicitly mentions that the position would entail "handling reimbursement questions regarding the coding, coverage, and reimbursement for Dermagraft." Cataldo Decl. Ex. F.

C. Analysis

The plaintiffs argue that a finding of personal jurisdiction can be made under either Federal Rule of Civil Procedure 4(k)(1)(A), which permits the exercise of personal jurisdiction over a defendant "who is subject to the jurisdiction of a court of general jurisdiction in the state where the district court is located," or Federal Rule of Civil Procedure 4(k)(2), which permits personal jurisdiction over a defendant who "is not subject to jurisdiction in any state's courts of general jurisdiction" so long as "exercising jurisdiction is consistent with the United States Constitution and laws." Because Shire is an alien corporation, satisfaction of either rule would support personal jurisdiction. However, because Shire Pharmaceuticals is a corporation created under the laws of Delaware, it can be subject to jurisdiction only under Rule 4(k)(1)(A). Here, because Rule 4(k)(1)(A) permits the exercise of personal jurisdiction for both of these defendants, no

analysis under Rule 4(k)(2) is necessary.

Under Rule 4(k)(1)(A), personal jurisdiction exists if two conditions are satisfied: (1) the forum state's long-arm statute permits service of process; and (2) the assertion of personal jurisdiction in accordance with that statute would not violate constitutional due process. See Touchcom, Inc. v. Bereskin & Parr, 574 F.3d 1403, 1411 (Fed. Cir. 2009).

1. Massachusetts's Long-Arm Statute

Although Federal Circuit precedent governs the due process analysis in patent cases, see 3D Sys., 160 F.3d at 1377, the Federal Circuit "defer[s] to the interpretation of a state's long-arm statute given by that state's highest court," id. Although state courts and the First Circuit have concluded that the Massachusetts long-arm statute reaches to the "limits allowed by the Constitution of the United States," Daynard v. Ness, Motley, Loadholt, Richardson & Poole, P.A., 290 F.3d 42, 52 (1st Cir. 2002), such language does not mean that the court can proceed to the due process analysis without considering whether the state long-arm statute is satisfied. Rather, as the Massachusetts Supreme Judicial Court ("SJC") has noted, "[personal] [j]urisdiction is conferred only when some basis for jurisdiction enumerated in the statute has been established." Tatro v. Manor Care, Inc., 625 N.E.2d 549, 550 (Mass. 1994) (internal quotation marks omitted); see also Morrill v. Tong, 453 N.E.2d 1221, 1227

(Mass. 1983) ("Although presented with jurisdictional facts sufficient to survive due process scrutiny, a judge would be required to decline to exercise jurisdiction if a plaintiff was unable to satisfy at least one of the statutory prerequisites.").

The Massachusetts long-arm statute permits the exercise of personal jurisdiction over a broad range of activities, including "(a) transacting any business in this commonwealth; (b) contracting to supply services or things in this commonwealth; . . . [or] (e) having an interest in, using or possessing real property in this commonwealth," but only when the "cause of action in law or equity aris[es] from" one of those activities. M.G.L. ch. 233A §3. The SJC has stated:

[W]e have read the "transacting any business requirement . . . broadly, in keeping with our view that the Massachusetts long-arm statute "functions as 'an assertion of jurisdiction over the person to the limits allowed by the Constitution of the United States.'" There is no reason to depart from this principle with respect to the "arising from" language, which occurs in the same section of the statute.

Tatro, 625 N.E.2d at 553-54 (citations omitted) (quoting Good Hope Indus., Inc. v. Ryder Scott Co., 389 N.E.2d 76, 79 (Mass. 1979)). There is no requirement that the cause of action arise entirely from the transaction of business within the commonwealth. See Good Hope Indus., 389 N.E.2d at 80 (long-arm statute is satisfied when cause of action "has arisen, at least in part, by virtue of" in-state transaction of business (emphasis added)).

For Shire, the plaintiffs have provided evidence that Dr.

Ornskov, in his capacity as Shire's CEO, has extensive contacts in Massachusetts, such as keeping an in-state office from which he conducts "hands-on" management of Shire's subsidiaries, including SRM, which has not contested personal jurisdiction and which is alleged to have directed its Dermagraft sales and marketing to Massachusetts residents, an allegation supported by the Boston-based job listing concerning Dermagraft reimbursements. Taken together with the uncontroverted allegations in the amended complaint that Shire is "involved in the manufacturing, marketing, and selling of the accused product in this case" and has "purposefully directed sales and marketing of its products to Massachusetts residents," Am. Compl. ¶9, this evidence results in the reasonable inference that Shire has engaged in in-state activities connected to the marketing and sale of Dermagraft, out of which the present claim arises. The plaintiffs have, therefore, made a sufficient prima facie showing that the cause of action "aris[es] from" Shire's "transacting any business in this commonwealth."

For Shire Pharmaceuticals, the job postings provided by the plaintiffs indicate that the company is involved with the marketing and distribution of SRM's products, including Dermagraft, and has specifically sought to hire employees in Massachusetts, including one to assist with Dermagraft reimbursements. Taken together with the uncontroverted allegations in the amended complaint that Shire

Pharmaceuticals "is involved in the manufacturing, marketing, and selling of the accused product" and has "purposefully directed sales and marketing of its products to Massachusetts residents," id. ¶10, the plaintiffs have made a prima facie showing that causes the court to conclude that the cause of action "aris[es] from" Shire Pharmaceuticals's "transacting any business in this commonwealth."

2. Due Process

Because the plaintiffs have made a prima facie showing that both Shire and Shire Pharmaceuticals fall within the ambit of the long-arm statute, a due process analysis is necessary.

The Federal Circuit, whose precedent governs the due process analysis, see 3D Sys., 160 F.3d at 1377, "employs a three-prong test, in which [it] determine[s] whether: (1) the defendant purposefully directed its activities at residents of the forum, (2) the claim arises out of or relates to those activities, and (3) assertion of personal jurisdiction is reasonable and fair," Breckenridge Pharma., Inc. v. Metabolite Labs., Inc., 444 F.3d 1356, 1363 (Fed. Cir. 2006) (citing Akro Corp. v. Luker, 45 F.3d 1541, 1545-46 (Fed. Cir. 1995)).

As explained earlier, the plaintiffs have presented evidence that both of the defendants at issue have extensive in-state contacts and that those contacts are related to the activities of SRM, including the marketing and distribution of Dermagraft. The

evidence, including the article headlined "CEO Calls Being in Mass. Crucial for Shire to Innovate," which describes Dr. Ornskov's move to Massachusetts and describes his "hands-on" approach to managing Shire's subsidiaries, including SRM, constitutes a prima facie showing that Shire "purposefully directed its activities at residents of the forum." Breckenridge Pharma., 444 F.3d at 1363. Although Shire is not the direct manufacturer of Dermagraft, the evidence presented shows that Shire exerts significant influence over SRM, which has itself purposefully directed its activities at Massachusetts residents under the "stream-of-commerce" theory of personal jurisdiction. See Nuance Commc'ns, Inc. v. Abbyy Software House, 626 F.3d 1222, 1233 (Fed. Cir. 2012). Shire presents itself as a passive holding company, but where there is evidence that a holding company has substantial managerial ties to allegedly infringing subsidiaries, a finding of personal jurisdiction is permissible. See id. at 1235 (citing Cardsoft, Inc v. Verifone Holdings, Inc., No. 08-098, 2009 WL 361069 (E.D. Tex. Feb. 10, 2009)). Although discovery may reveal ultimately Shire's managerial ties to SRM to be moderate, the plaintiffs have made the prima facie showing necessary to survive Shire's motion to dismiss.

The evidence of Shire Pharmaceuticals's in-state hiring and job listings for Massachusetts also causes the court to conclude that it has "purposefully directed its activities at residents of the forum." Breckenridge Pharma., 444 F.3d at 1363. Making hiring

decisions for positions within the forum state and directly employing employees in that state are not "'[r]andom,' 'fortuitous,' or 'attenuated' contacts," Red Wing Shoe Co., Inc. v. Hockerson-Halberstadt, 148 F.3d 1355, 1358 (Fed. Cir. 1998) (quoting Burger King Corp. v. Rudzewicz, 471 U.S. 462, 475 (1985)), and create a "substantial connection" with the forum. Id. (quoting Burger King, 471 U.S. at 475). Therefore, the first prong of the due process test is satisfied with respect to both Shire and Shire Pharmaceuticals.

The second prong, which examines whether the claim arises out of or relates to the defendants' in-state activities, closely resembles the earlier inquiry under the state long-arm statute. See United Elec., Radio & Mach. Workers of Am. v. 163 Pleasant St. Corp., 960 F.2d 1080, 1087 (1st Cir. 1992) ("The [long-arm] statute's relatedness requirement mirrors a key constitutional requirement for the exercise of specific jurisdiction."). In fact, the Federal Circuit has noted that it is less demanding than the long-arm test, concluding that "'it [is] significant that the constitutional catch-phrase ['arise out of or relate to'] is disjunctive in nature,' indicating 'added flexibility and signal[ing] a relaxation of the applicable standard' from a pure 'arise out of' standard." Akro, 45 F.3d at 1547 (alterations in original) (quoting Ticketmaster-New York, Inc. v. Alioto, 26 F.3d 201, 206 (1st Cir. 1994)). For the reasons provided in the long-

arm analysis, then, the plaintiffs have satisfied the second prong of the due process inquiry.

For the third prong, which concerns the fairness of personal jurisdiction, "the burden of proof is on the defendant, which must 'present a compelling case that the presence of some other considerations would render jurisdiction unreasonable.'" Id. at 1363 (quoting Burger King, 471 U.S. at 476-77). "In general," the Federal Circuit has noted, "these cases are limited to the rare situation in which the plaintiff's interest and the state's interest in adjudicating the dispute in the forum are so attenuated that they are clearly outweighed by the burden of subjecting the defendant to litigation within the forum." Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1568 (Fed. Cir. 1994). Shire and Shire Pharmaceuticals have emphasized that they lack a formal corporate presence in Massachusetts. See Stewart Decl.; Rosenberg Decl. However, the evidence provided by the plaintiffs indicates that the three defendants are each part of a well-integrated corporate family with substantial in-state connections and indicates that the burden of in-state litigation does not outweigh the plaintiffs' choice of forum. Therefore, the defendants have not carried their burden of demonstrating that this is a "rare situation" that would generate unfairness in violation of the due process clause. Beverly Hills Fan, 21 F.3d at 1568.

Because the plaintiffs have made a prima facie showing that

both the long-arm statute and due process have been satisfied, the court finds that the motion to dismiss the claims against Shire and Shire Pharmaceuticals for lack of personal jurisdiction is not meritorious. This determination is, however, without prejudice to later reconsideration. See Boit v. Gar-Tec Prods., Inc., 967 F.2d 671, 676 (1st Cir. 1992) (when court denies motion to dismiss for lack of personal jurisdiction, it defers determination of the motion until trial); see also Arctic Corner, Inc. v. United States, 845 F.2d 999, 1000 (Fed. Cir. 1988) (court may address jurisdiction sua sponte whenever it appears in doubt); Consolidation Coal Co. v. United States, 351 F.3d 1374, 1378 (Fed. Cir. 2003) (court may address jurisdiction at any stage in the proceedings).

III. FAILURE TO STATE A CLAIM

A. Legal Standard

Because the application of Federal Rule of Civil Procedure 12(b)(6) is a procedural question, the law of the First Circuit governs the inquiry. See Polymer Indus. Prods. Co. v. Bridgestone/Firestone, Inc., 347 F.3d 935, 937 (Fed. Cir. 2003).

In considering a motion to dismiss under Rule 12(b)(6) for failure to state a claim upon which relief can be granted, the court must "take all factual allegations as true and . . . draw all reasonable inferences in favor of the plaintiff." Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 96 (1st Cir. 2007); see also Maldonado v. Fontanes, 568 F.3d 263, 266 (1st Cir. 2009). The

court must "neither weigh[] the evidence nor rule[] on the merits because the issue is not whether the plaintiffs will ultimately prevail, but whether they are entitled to offer evidence to support their claims." Day v. Fallon Cmty. Health Plan, Inc., 917 F. Supp. 72, 75 (D. Mass. 1996). A motion to dismiss should be denied if a plaintiff has shown "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007); see also Rodriguez-Ortiz, 490 F.3d at 95-96 (applying the Bell Atlantic standard to a claim under the Private Securities Litigation Reform Act); Morales-Tanon v. Puerto Rico Elec. Power Auth., 524 F.3d 15, 18 (1st Cir. 2008) (applying the Bell Atlantic standard to a claim under 42 U.S.C. §1983).

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint include a "short and plain statement of the claim showing that the pleader is entitled to relief." This pleading standard does not require "detailed factual allegations," but does require "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Bell Atl., 550 U.S. at 555. A court may disregard "bald assertions, unsupportable conclusions, and opprobrious epithets." In re Citigroup, Inc., 535 F.3d 45, 52 (1st Cir. 2008). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949 (2009) (emphasis added).

"Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Id. (quoting Bell Atl., 550 U.S. at 557).

Ordinarily, a court will not consider documents outside of the pleadings in a motion to dismiss. Rivera v. Centro Medico de Turabo, Inc., 575 F.3d 10, 15 (1st Cir. 2009); Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). From this rule, the First Circuit makes a "narrow exception for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiff's claim; or for documents sufficiently referred to in the complaint." Watterson, 987 F.2d at 3-4; Beddal v. State St. Bank & Trust, Co., 137 F.3d 12, 16-17 (1st Cir. 1998) (when "a complaint's factual allegations are expressly linked to - and admittedly dependent upon - a document (the authenticity of which is not challenged) that document effectively merges into the pleadings and the trial court can review it in deciding a motion to dismiss under Rule 12(b)(6)").

B. Analysis

1. Induced Infringement

The plaintiffs allege that Shire and Shire Pharmaceuticals are liable for indirect infringement under 35 U.S.C. §271(b), which provides that "[w]hoever actively induces infringement of a patent shall be liable as an infringer." To state a viable claim for

induced infringement, a plaintiff must allege facts showing that the defendant: (1) "knew of the patent"; (2) "actively and knowingly aid[ed] and abett[ed] another's direct infringement"; and (3) possessed specific intent. DSU Med. Corp. v. JMS Co., Ltd., 471 F.3d 1293, 1305 (Fed. Cir. 2006) (alterations in original) (internal quotation marks omitted) (quoting Water Techs. Corp. v. Calco, Ltd., 850 F.2d 660, 668 (Fed. Cir. 1988)). As the Supreme Court has recently clarified, such a claim "requires knowledge that the induced acts constitute patent infringement," Global-Tech Appliances, Inc. v. SEB S.A., 131 S. Ct. 2060, 2068 (2011), not merely knowledge of the acts themselves, although a showing of willful blindness is also satisfactory, see id. at 2074. A defendant's mere negligence or recklessness is insufficient. See Commil USA, LLC v. Cisco Sys., Inc., 720 F.3d 1361, 1366 (Fed. Cir. 2013).

The Federal Circuit has clarified that the heightened pleading standard of Bell Atlantic and Iqbal applies to indirect infringement claims, including those for induced infringement. See In re Bill of Lading Transmission, 681 F.3d 1323, 1336 (Fed. Cir. 2012). Therefore, although the plaintiff need not "allege facts that prove all aspects of its claims, or at the very least make those claims probable," id. at 1341, an induced infringement claim will not pass muster under 12(b)(6) when the plaintiff "does not allege any facts to support a reasonable inference that [the

defendant] specifically intended to induce infringement . . . or that it knew it had induced acts that constitute infringement," Superior Indus., LLC v. Thor Global Enters. Ltd., 700 F.3d 1287, 1296 (Fed. Cir. 2012).

The amended complaint itself contains few allegations concerning induced infringement, noting only that "[u]pon information and belief, Shire and Shire Pharmaceuticals actively induce and have induced, with the specific intent to induce, under 35 U.S.C. §271(b), SRM's infringement" of the two patents. Am. Compl. ¶¶25, 34.

There is limited factual support in the complaint for these allegations. The complaint makes the general assertion that "[u]pon information and belief," these defendants are "involved in the manufacturing, marketing, and selling of the accused product in this case." Id. ¶¶9, 10. The complaint also alleges that in 2011, MIT sent letters to SRM and Shire Pharmaceuticals "informing them of the patents-in-suit and inviting them to engage in discussions with MIT." Id. ¶21. Finally, complaint states that in 2012, the plaintiffs sent a letter, actually alleging infringement, to SRM alone. Id. ¶22.

The plaintiffs argue that, in determining the sufficiency of the pleadings, the court should consider the evidence in affidavits concerning Dr. Ornskov's oversight of SRM and Shire Pharmaceuticals's involvement with SRM's hiring, marketing, and

distribution. Pls.' Opp. to Mot. at 17. Although the plaintiffs' affidavits were properly considered to assess personal jurisdiction under Rule 12(b)(2), they may not be considered with respect to the Rule 12(b)(6) motion to dismiss because these documents were not referenced in the complaint itself. See Watterson, 987 F.2d at 3-4. If this evidence were considered, the motion to dismiss Shire and Shire Pharmaceuticals would be converted into a motion for summary judgment. See Fed. R. Civ. P. 12(d). Doing so would require the submission of additional evidence, id., and probably discovery which would impede the progress of this case, see Fed. R. Civ. P. 56(d). It is, therefore, not appropriate to consider the affidavit evidence in deciding the pending Rule 12(b)(6) motion to dismiss.

The allegations in the complaint and the letters it references are not sufficient to satisfy the pleading standard established in Iqbal and Bell Atlantic. The allegations that the defendants are "involved in the manufacturing, marketing, and selling" of Dermagraft might be sufficient for a claim of direct infringement. See In re Bill of Lading, 681 F.3d at 1335 (noting that direct infringement claims are not subject to stringent pleading requirements). They do not, however, adequately support the more demanding specific intent requirement for a finding of induced infringement. See DSU Med. Corp., 471 F.3d at 1305. Furthermore, these allegations, without any other support in from within the

complaint, do not qualify as "non-conclusory, non-speculative" facts from which the court can draw reasonable inferences in the plaintiff's favor. Schatz v. Republican State Leadership Comm., 669 F.3d 50, 55 (1st Cir. 2012).

The court can consider the 2011 and 2012 letters in its evaluation of the sufficiency of the pleadings because they are referenced in the complaint. See Am. Compl. ¶¶21-22; Beddal, 137 F.3d at 16-17. However, the contents of those letters are also insufficient to support the claims of induced infringement. Because the letters were sent to SRM and Shire Pharmaceutical, but not Shire, the complaint alleges no facts to support the claim that Shire had the specific intent necessary for induced infringement. Although Shire Pharmaceuticals received a 2011 letter, that letter explicitly notes that MIT had "not yet fully evaluated the relationship between Shire's Dermagraft product and MIT's patents, and in particular [had] not assessed the possibility that Dermagraft and/or its manufacture, use or sale might fall within the scope of one or more MIT claims." July 27, 2011 Letter. The complaint also does not allege that the contents of the 2012 letter, which contained an explicit assertion that SRM was infringing these patents, were ever communicated to Shire Pharmaceuticals or Shire, which might be sufficient to support the allegations that those defendants had knowledge of infringement and chose to proceed regardless. See Superior Indus., 700 F.3d at

1296.

The court's conclusion in this case is consistent with the reasoning of other district courts confronted with motions to dismiss induced infringement claims under 12(b)(6). In Stephenson v. Game Show Network, LLC, for example, the district court found that where the "plaintiff does not provide facts which plausibly show that one defendant, via the corporate relationship, specifically intended the other to infringe and knew that the acts constituted infringement," the plaintiff had failed to state a claim for induced infringement. 933 F. Supp. 2d 674, 681 (D. Del. 2013). Similarly, in Oy Ajat, Ltd. v. Vatech America, Inc., the district court held that where the plaintiff had not pled that a corporate parent had received notification of a corporate subsidiary's infringement, it was necessary to dismiss the claims for past induced infringement. C.A. No. 10-4875 (PGS), 2011 WL 1458052 (D.N.J. Apr. 14, 2011).

Because the amended complaint does not contain factual allegations sufficient to support claims of induced infringement against Shire and Shire Pharmaceuticals, those claims must be dismissed.

2. Willful Infringement by Shire

Because the factual allegations in the amended complaint are insufficient to state a claim against Shire for induced infringement, and because the amended complaint contains no

allegations concerning other forms of infringement, direct or otherwise, by Shire, any claims that Shire's infringement was willful must also be dismissed.

IV. LEAVE TO AMEND

In their opposition to this motion, the plaintiffs request that, if the court finds the pleadings to be inadequate, they be granted leave to amend their complaint. Pls.' Opp. to Mot. to Dismiss at 18.

Under the Federal Rules of Civil Procedure, the court may permit a party leave to amend its pleadings, and it "should freely give leave when justice so requires." Fed. R. Civ. P. 15(a)(2); see also Foman v. Davis, 371 U.S. 178, 182 (1962). Leave to amend should be allowed unless there is an "apparent or declared reason – such as undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, futility of amendment, etc." Foman, 371 U.S. at 182; see also Glassman v. Computervision Corp., 90 F.3d 617, 622 (1st Cir. 1996).

Here, the court discerns no "apparent or declared reason" to deny the plaintiffs' request. The request to amend has been made early in the proceedings. There is also nothing to suggest that the plaintiffs' request is made in bad faith or is intended to slow the progress of this case. Nor will the defendants be unfairly

prejudiced by an amendment. The evidence presented in connection with the motion to dismiss for lack of personal jurisdiction suggests an amendment may not be futile. However, the court will, if necessary, address that issue on a motion to dismiss the possible Second Amended Complaint.

V. ORDER

Accordingly, it is hereby ORDERED that:

1. Defendants Shire PLC's and Shire Pharmaceuticals, Inc.'s Motion to Dismiss for Lack of Personal Jurisdiction and for Failure to State a Claim Upon Which Relief Can Be Granted (Docket No. 26) is ALLOWED. The claims against Shire and Shire Pharmaceuticals are DISMISSED without prejudice.

2. If there is a proper basis to do so, plaintiffs shall, by February 21, 2014, file a Second Amended Complaint. Defendants shall respond to any Second Amended Complaint by March 21, 2014. If a motion to dismiss is filed, plaintiffs shall respond within 14 days.

2. Defendants Shire PLC's and Shire Pharmaceuticals, Inc.'s Request for Oral Argument on Motion to Dismiss (Docket No. 28) is DENIED as MOOT.

/s/ Mark L. Wolf
UNITED STATES DISTRICT JUDGE